Chlorine Dioxide Gas: Decontamination Validation Made Simple

This paper highlights some of the reasons why gaseous chlorine dioxide (CD) provides an easy and more effective manner of validation of the decontamination process. In performing the decontamination, the FDA states, "uniform distribution of the defined concentration of decontaminating agent should be evaluated concurrent with these studies chemical indicators may also be useful as a qualitative tool to show that the decontaminating agent reached a given location".[1] Chemical indicators, as stated in its name, only give an indication of presence. They do not indicate that the sterilant concentration was sufficient. They do not indicate the sterilant had adequate contact time. They only indicate that the sterilant reached the location. That is why ClorDiSys' CD generators have integrated, real time, validated concentration monitoring[2]. ClorDiSys is proactive in providing what the FDA is asking for, concentration monitoring for the decontamination process. Since CD is a greenish-yellow gas it is easily read using a UV-VIS spectrophotometer. It provides a reliable, and more importantly, repeatable concentration monitoring. Runs have been performed in isolators and rooms and it was shown that the CD concentration did not vary across multiple locations throughout the cycle. Remember CD is a true gas and as such it acts as a true gas and distributes completely and evenly, following the gas laws of physics. This makes validation much easier and simpler.

Using a gas makes the validation effort easier compared to a vapor such as vapor phase hydrogen peroxide (VPHP) or peracetic acid (PA). Since CD is a gas at room temperatures, it is not subject to temperature swings or differentials in the environment. When using VPHP, if the temperature changes, as it does when the HVAC turns on or off, then the concentration changes and therefore the decontamination efficacy changes. Placement of a load, and the load itself, can affect VPHP distribution, limiting concentration at some points. In a transfer isolator with no load, the VPHP concentration was 2.36 mg/L, with a load the concentration was 1.87 mg/L. To confuse the validation efforts even more, a workstation isolator had the same concentration with and without a load. This was surmised to be a result of the greater amount of PVC in the isolator.[3] Using CD, none of these issues affect the cycle. If there is something that reacts with the gas, the equipment automatically adds more gas. A cycle can be set such that if the concentration ever falls below the set point, then the exposure time pauses until the concentration is back at the set point. This allows the total exposure time at concentration to always be consistent. A cycle can also be set up to control the process based on accumulated dosage. The run report from the system contains the cycle parameters and all the important real time data, and will inform the user when the exposure timer was paused, thereby fully documenting the cycle from beginning to end.

Validation is also made easier when using CD since it is not affected by different materials of construction. For example, galvanized steel breaks down VPHP. [4] Galvanized steel is typically used in the duct work for air supply and exhaust in rooms. Water is a big issue if present when performing a VPHP decontamination. VPHP cannot decontaminate the water or the areas beneath the water since it does not penetrate water. CD is water soluble and will penetrate water and decontaminate the water and the area under the water. Water can easily be present in a room or isolator since the first step of any decontamination is cleaning and water is typically used during this process. Paper products are also a concern with VPHP. It breaks down or absorbs VPHP thereby scavenging it from other areas.[5] Sterilants are absorbed by paper, but since CD is monitored by a photometer, more gas cab be automatically added so that the concentration remains constant in the chamber. Therefore, the decontamination remains constant despite materials that may affect the sterilant.

ClorDiSys' chlorine dioxide gas process was extensively tested to enable the CD systems to be registered with the United States Environmental Protection Agency (US-EPA) as a sterilant.[6] The US-EPA defines Sterilizers (Sporicides): Used to destroy or eliminate all forms of microbial life including fungi, viruses, and all forms of bacteria and their spores. Spores are considered to be the most difficult form of microorganism to destroy.

Validation is performed to confirm that a process works and is repeatable. The science of CD being a gas that distributes completely and evenly, the photometric measurement and concentration control, its disregard towards external factors (temperature gradients, load, and materials), and the EPA registration assuring efficacy, all greatly support validation.

References:

[1] Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice, Sept 2004, pp47.

[2] "Validation of Photometric Measurement of Chlorine Dioxide Gas", Saumil Shah1, Todd Sickler2, Lisa Smith2, Lanie Wallace3, Vipin K. Rastogi31. Science & Technology Corp., Edgewood, MD; 2. SAIC/GEO-Centers, Inc., PO Box 68, Gunpowder Club, MD;3. Microbial & Analysis Products Team, R&T Directorate, US Army – ECBC, APG, MD, presented at Decon 2005 conference.

[3] Real-Time Monitoring of Vapor Phase Hydrogen Peroixde for Cycle Development" Claire Fritz, Don Eddington & Dennis Cantoni. Steris Publication M1379,

[4] Edited by Sarah Dun, Joseph Wood, Blair Martin, Presentation for "Workshop on Decontamination, Cleanup, and Associated Issues for Sites Contaminated With Chemical, Biological, or Radiological Materials", Contract No. EP-C-04-056, Office of Research and Development, U.S. Environmental Protection Agency, Title: "Use of HVAC Systems in Building Decontamination" Presented by Tina Carlsen, Lawrence Livermore National Laboratory, Feb 24, 2005.

[5] Joint Service Pollution Prevention Technical Opportunity Handbook (JSPPTOH), LOW-TEMPERATURE OXIDATIVE STERILIZATION METHODS FOR STERILIZING MEDICAL DEVICES, Revision Date 4/04.

[6] US Environmental Protection Agency website http://www.epa.gov/oppad001/chemregindex.htm , ClorDiSys Solutions, Inc. Registration number 80802-1.